IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFFS: **Joy Essman** **Case No. 2:12-cv-00277** **Christine Wiltgen** **Case No. 2:12-cv-01216** **Shirley Walker** **Case No. 2:12-cv-00873** **Julie Wroble** **2:12-cv-00883** **Nancy Jo Williams** **Case No. 2:12-cv-00511**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL OPINION TESTIMONY OF DR. GREGORY T. BALES, M.D.

I. PRELIMINARY STATEMENT

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, the expert testimony of Dr. Gregory T. Bales, M.D. ("Dr. Bales"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs the admissibility of expert testimony). Dr. Bales seeks to offer general opinions regarding certain products manufactured and marketed by Defendant Ethicon, Inc. ("Ethicon") for the treatment of pelvic organ prolapse

("POP"), including Gynemesh PS and Prolift, including the Prolift-M.[1] His opinions are proffered in the Defense Expert General Reports of [Dr. Bales] ("Bales Report")[2] and in his deposition testimony of April 1, 2016.[3] Plaintiffs now seek to exclude or limit Dr. Bales's opinions regarding Ethicon's devices to treat POP as set forth herein to reflect:

- Dr. Bales "cherry-picked" his research materials, deliberately citing only to those supporting his opinions, while ignoring those that do not, thereby rendering many of his opinions unreliable and subject to exclusion;
- Dr. Bales is not an expert in the design or biomechanics of any medical devices, including devices manufactured and marketed for the treatment of POP; neither is he an expert in pathology, regulatory affairs, industry standards or warnings,[4] and as such, his opinions related to those topics must be excluded; and
- Dr. Bales admitted that he treats "more complications [from mesh] than [he] care[s] to" and cannot now testify otherwise. (Ex. B, 32:19-22)

In addition to the foregoing, Dr. Bales also seeks to proffer general opinions regarding certain products manufactured and marketed by Ethicon for the treatment of SUI. These devices include the TVT-Retropubic (namely the TVT-classic and the TVT Exact, collectively referred to herein as "TVT") and the TVT-Obturator ("TVT-O"). Dr. Bales's opinions on the Ethicon devices used in the treatment of SUI are set forth in the Bales Report and in Dr. Bales's deposition testimony of April 2, 2016.[5] Plaintiffs move now to limit some of his opinions regarding Ethicon's

[1] Dr. Bales has not used the Prosima device and offers no opinions about it.

[2] The Bales Report is attached hereto as Exhibit A-1. Citations to the Bales Report are in the form (Ex. A-1, ___.).

[3] Relevant excerpts of Dr. Bales's deposition of April 1, 2016 are attached hereto as Exhibit B. Citations to it will be in the form (Ex. B, ___:___.).

[4] Any of Dr. Bales's opinions regarding biomechanics, pathology, regulatory affairs, industry standards or warnings related to products Ethicon manufactures and markets for the treatment of stress urinary incontinence ("SUI") should likewise be excluded, since Dr. Bales is not qualified to proffer them.

[5] Relevant excerpts of Dr. Bales's deposition of April 2, 2016 are attached hereto as Exhibit C. Citations thereto are in the form (Ex. C, ___:___.).

SUI devices as more fully set forth herein.

II. FACTUAL STATEMENT – DR. BALES'S QUALIFICATIONS[6]

Dr. Bales is a board certified urogynecologist[7] who treats patients, performs surgeries, teaches, and pursues other academic endeavors as a member of the faculty at the University of Chicago and its affiliated hospitals.[8] He also has staff privileges at Munster Community Hospital in Munster, Indiana.[9] He has utilized the full panoply of treatment options during the course of his career to treat patients suffering from SUI and POP.[10] Dr. Bales has an undergraduate degree in biochemistry[11] but has otherwise completed no advanced studies, in the scientific, chemical or structural makeup of medical devices-- including Ethicon's TVT and POP devices-- which are the subjects of the current litigation.[12] He also admits that he has no expertise in pathology, regulatory affairs affecting the medical device industry, industry standards governing Ethicon or warnings as they relate to medical devices.[13]

III. LEGAL STANDARD

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

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[6] Dr. Bales's Curriculum Vitae ("CV") is attached hereto as Exhibit D. Cites to it will be in the form (Ex. D, ___).
[7] (Ex. D, 1.)
[8] (*Id.*)
[9] (*Id.*)
[10] (*See e.g.*, Ex. B, 19:11-13; 23:9-17) (Ex. C, 8:17-9:9.)
[11] (Ex. D, 1.)
[12] Dr. Bales has a Bachelor of Science degree in biochemistry, a medical degree, and has completed a fellowship in female and reconstructive urologic surgery. (*Id.*)
[13] (Ex. B, 45:4-46:3.)

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a "gatekeeping function" in determining whether expert testimony is both reliable and relevant and, thus admissible, under Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,") (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) -- the statute imposing duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence -- this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See*, *Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is "scientifically valid" and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W.Va. July 14, 2011).).

IV. LEGAL ARGUMENT

A. DR. BALES'S OPINIONS MUST BE EXCLUDED TO THE EXTENT THAT THEY ARE GROUNDED SOLELY IN DR. BALES'S SELECTIVE REVIEW OR CHERRY-PICKING OF THE RELEVANT SCIENTIFIC SCHOLARSHIP AND DO NOT ACCOUNT FOR EXTENSIVE SCHOLARSHIP CONTRADICTING DR. BALES'S OPINIONS.

This Court has previously held that expert witnesses may not ground their opinions in merely a selective review of academic or scientific literature, choosing only materials that support

their opinions, while ignoring literature that does not. Such an approach is unreliable under *Daubert* and its progeny:[14]

> An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively chooses his support from the scientific landscape. If the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.

Wilkerson v. Boston Scientific Corp., C. A. No. 2:13-cv-04505, 2015 WL 2087048 at *9 (S.D.W.Va May 5, 2015)(internal citations and quotations omitted.).

Dr. Bales engages in just such cherry-picking of scientific evidence in his attempt to support some of his opinions, while he ignores a plethora of scientific scholarship refuting his opinions. When asked very generally how he chose materials to include in his report, Dr. Bales admitted to there being "a voluminous amount of information," (Ex. B, 12:16), and further, that he engaged in a process of "pick[ing] and choos[ing]" in an effort to find the appropriate "broad array" of needed Level 1 evidence. (*Id*. 12:20-22.) While he considers his opinions to be unbiased, (*id*. 12:6-8), it is clear that, in truth, some of them are anything but. Those opinions must now be excluded. *See Kumho Tire Co.*, 526 U.S. at 152; *see also Wilkerson*, 2015 WL 2087048 at *9.

1. Dr. Bales's Opinion that the Complication Rates for Certain Native Tissue Procedures Exceed 30% Must Be Excluded Because He Ignored Relevant Studies Establishing Complication Rates for the Procedures Are Much Lower.

Dr. Bales admitted during his deposition testimony that he cited to an outdated version of a scientific article despite knowing both that it had been updated in key respects and that the more recent version supported a substantially lower risk of complications for at least some of the native tissues repairs discussed in the original report:

[14] *See Kumho Tire Co.*, 526 U.S. at 152 (expert testimony must be both reliable and relevant.).

Q. I'm going to start with the Weber article that you cited in your report; and you are aware, Dr. Bales, that the Weber article from 2001 was re-analyzed with modern definitions of prolapse and success by Chmielewski, correct?

A. Yes.

Q. I'm curious why you cited the 2001 Weber article rather than the 2011.

A. So, I guess if that's a question, again it's impossible to cite every article that's out there, so I picked certain ones.

(Ex. B, 60:11-21.)

Dr. Bales's failure to use the updated Weber article led him to conclude that some vaginal surgeries using native tissue are far less successful than more recent scholarship indicates. (*Id*. 61:4-62:9.) When asked to explain his apparent serious lapse in scholarly methodology, Dr. Bales did not refute the truth of the updated Weber article but, instead, replied that he simply could not cite to everything. (*Id*. 62:10-63:2.) Dr. Bales's non-answer does nothing to change the fact that it renders his opinion regarding the complication rates of some native tissue repair to be hopelessly flawed:

Q. And you will certainly agree with me that a 5 percent symptomatic recurrence and no subjects requiring additional surgery is very different from the recurrence of 30 percent or more that you cite in your paper, right?

A. So you are asking if 30 is different than 5, and the answer is yes, 30 is different than 5.

(*Id*. 63:3-10.)

Dr. Bales's attempt to cover his bias with the bald assertion that the updated Weber report is an "anomaly" likewise fails. He claims that many papers support his opinion that the

complication rate for native tissue repairs exceeds 5% ***but he fails to cite any of them in his testimony***, rendering his opinion that the updated Weber report is an anomaly to be grounded in mere speculation and subject to exclusion. *See Huskey v. Ethicon*, 29 F.Supp.3d 691, 727-729 (S.D.W.Va 2014)(expert opinion must be grounded in more than speculation.)

Dr. Bales also failed to cite a report other than Weber that places the complication rate for the native tissue repairs in questions at 7% ***even though he cited to exactly the same study for other points he makes in the Bales Report***. (*See* Ex. B, 64:19-67:13.) And finally, Dr. Bales ignored a study from 2013 which cited low complication rates for native tissue repairs and concluded that native tissue procedures "should be the first choice in treating primary POP providing use of adequate surgical technique." (*Id*. 68:18-69:11)(quoted material 69:4-6.).

Finally, Dr. Bales failed to consider an important study that compared the three-year cure rates between traditional vaginal surgery without mesh and procedures using Prolift, concluding there was little to no difference. (*Id*. 69:16-70:16.) Even while admitting that this study found comparable cure rates between the procedures, Dr. Bales continued to assert that the complication rate for native tissue repairs exceeds 30%. (*Id*. 70:17-71:6.)

Dr. Bales clearly did not countenance significant scientific scholarship refuting his opinion that the complication rates for certain native tissue repairs could exceed 30% and also failed to cite to significant research that supported his opinion. (*Id*. 71:3-21.) In the face of such clear research bias, each and every one of Dr. Bales's opinions that the complication rates for certain native tissue POP repairs exceed 30% must be excluded as not supported by overwhelming current scientific literature.

2. Dr. Bales's Opinion that Dyspareunia is Not a Significant Risk of POP Surgeries Using Mesh is Not Supported by the Literature and Must Be Excluded.

Quite early in his deposition, Dr. Bales testified that he treats "more complications [from] mesh than [he] care[s] to." (Ex. B, 32:19-22.) And yet, citing only a single scientific study to support his opinion, Dr. Bales states that the only unique risk with Prolift and/or Gynemesh devices is mesh erosion and exposure. In so opining, he downplays significant complications of such devices and also utterly ignores that even the study he cites, himself, finds a correlation exists between mesh surgeries for POP and the incidence of complications such as dyspareunia. (*Id*. 81:16-83:7.) That dyspareunia is not an uncommon side effect of POP surgery, causing pain that is of a different quality than with other vaginal surgery, is well-supported in the scientific literature. (*See e.g., Id*. 81:16-86:11.) Any opinion of Dr. Bales to the contrary is not properly supported and should be excluded as unreliable:

> Q. So your opinion that the quality of dyspareunia and vaginal pain that occurs after mesh surgery is no different from that that can occur with other prolapse surgery?
>
> A. Yes. It may not be any different all at.
>
> Q. ***And you are ignoring the dozens of articles that would say something differently, correct?***
>
> * * * *
>
> Q. Can you cite any paper that would support your opinion that the pain associated with vaginal mesh is no different . . . . Can you cite any paper that says that pain that occurs after mesh procedure is no different from that occurring with any other native tissue repairs?
>
> A. I'm not so sure there has been a comparative study, so I can't say that.

(*Id*. 103:7-15; 103:24-104:9.)(emphasis added.)

3. Dr. Bales Ignores Scientific Literature That Refutes His Opinion that Mesh Shrinkage is Not Clinically Significant and His Opinion Must Be Excluded.

Dr. Bales ignores scholarship contrary to his opinions that mesh shrinkage that occurs after implants is clinically insignificant. (*Id*. 88:1-90:20.) For example, Dr. Bales discounts the 2016 Cochrane Review, a well-respected piece of scholarship, which concludes that partly due to mesh contracture, the risks of using mesh in vaginal surgery are not outweighed by the benefits of using it in "primary" surgeries, (*id*. 108:1-3), that the benefits of using mesh in surgeries with women with a higher risk of recurrences have not been conclusively-established, (*id*. 108:3-7), and that even newer lightweight transvaginal meshes (that are allegedly improvements over earlier devices) should only be used in hospitals at the direction of ethics committees. (*Id*. 108:14-16.)

Nevertheless, Dr. Bales offers the opinion that mesh contraction, to the extent it exists at all, is no more than a naturally-occurring trait of mesh that does not lead to complications of clinical consequence. (*Id*. 117:20-118:1.) In arriving at this opinion, Dr. Bales ignores contrary scientific scholarship like the Cochrane Review, along with another study by the same researchers, (*id*. 117:2-9; 118:13-19) that stand in direct opposition to his opinion that mesh contraction is not clinically-significant. (*Id*. 118:2-119:12.) In fact, Dr. Bales even admits that his opinion is contrary to substantial contradictory scholarship:

> Q. And you are aware that there are dozens, literally, of articles describing mesh contracture and the clinical symptoms, primarily pain, associated with it, correct?
>
> A. I'm aware that both those things exist, and I'm certainly aware that mesh contractures occur . . .

(*Id*. 119:13-19.)

To support his own very questionable opinion, Dr. Bales chose to cite to only one article out of the dozens in existence on the subject of mesh contraction (many of which contradict him).[15] (*Id*. 122:6-10.) The paper he cited was written by Dr. Dietz, a consultant for mesh manufacturers. (*Id*. 123:13-20.) Dr. Dietz used translabial ultrasound rather than transvaginal to derive data for his study, a method that Dr. Bales admitted to having little familiarity with, thereby making it impossible for Dr. Bales properly to assess the merit of Dr. Dietz's results. (*Id*. 123:21-124:8.) Dr. Bales also admitted that the mesh device studied by Dr. Dietz was not an Ethicon product at all, (*id*. 131:1-18), further limiting its relevance to Dr. Bales's opinion regarding mesh contracture and its clinical impact on the women who experience it after receiving Ethicon implants. Ultimately, even Dr. Bales admits that mesh shrinkage is a concern for urologists and urogynecologists:

> Q. And do you agree with the statement that mesh shrinkage is a phenomenon which has become a rising concern in urogynecology since the widespread use of vaginal mesh?
>
> A. I think it's a concern for urogynecologists, urologists. Anybody who is using vaginal mesh, it would be a concern.

(*Id*. 140:18-24.)

And yet, he never deviates from his opinion that shrinkage is of no clinical importance. This opinion is contradicted by scientific evidence that is well-supported, contrary to Dr. Bales's opinion, but simply ignored by him. Dr. Bales's opinion is unreliable and must be excluded.[16]

[15] During the deposition, Plaintiffs brought to Dr. Bales's attention several articles refuting his points regarding mesh contracture, articles and studies which also discuss Ethicon devices specifically. (*See e.g., Id*. 134:14-138:24.)

[16] For like reasons, Plaintiffs also move that Dr. Bales's closely-related opinions that mesh contracture does not cause dyspareunia also must be excluded. (*Id*. 148:13-149:6.)

B. DR. BALES IS NOT QUALIFIED TO PROFFER OPINIONS REGARDING THE CHEMICAL, STRUCTURAL, OR BIOMECHANICAL MAKEUP OF ETHICON'S MEDICAL DEVICES INCLUDING GYNEMESH PS, THE PROLIFT, THE TVT OR THE TVT-O OR PERTAINING TO ANY OF THEIR COMPONENT PARTS AND ALL OF HIS OPINIONS RELATED TO SUCH MUST BE EXCLUDED.

The Bales Report includes numerous opinions that Dr. Bales, as a practicing urogynecologist lacking significant training in chemical or structural engineering and/or in biomechanics, is simply unqualified to proffer. As such, Dr. Bales's opinions must be excluded pursuant to Rule 702. *See* Rule 702 (an expert must be qualified by "knowledge, skill, experience, training, or education."). The opinions to be excluded are:

- that clinical data is "inconsistent" to support Plaintiffs' claims that the mesh used in Ethicon's devices "degrades, is cytotoxic, leads to an adverse significant inflammatory response, and [ ] causes sarcoma formation or cancer;"(Ex A1, 9, 20-21.)
- that Prolene mesh has evidence of long-term biocompatibility; (*id*.)
- that evidence shows that mesh devices with larger pores and lighter mesh than present in the Prolift have not withstood clinical scrutiny and are not safer than Prolift devices; (*id*. 10.) and
- that Prolene's inflammatory responses were well-known before the material was used in the Prolift. (*Id*. 15.)

Nothing in Dr. Bales's education or training provides him with the experience needed to proffer the above-referenced opinions. Simply, because he has expertise in urogynecology does not render him also capable of offering expert opinion outside his field. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 697-98 (W.D.N.C. 2003) ("As Defendant points out, any expert including physicians, must have the specialized knowledge or skill in the specific area in

which the testimony is proffered."). Dr. Bales has no such specialized knowledge or skill, evidenced not only by his resume but also by his testimony that he has no understanding of the pathology or histology of mesh devices (Ex. B, 45:4-13). It is clear that Dr. Bales is not qualified to render the opinions regarding the chemical and biomechanical properties of the Ethicon POP or SUI devices or their components that he proffers in the Bales Report and in his deposition testimony and such should be excluded in full. Also excluded should be any and all opinions that Dr. Bales proffers regarding regulatory affairs or any industry standards or warnings since he admitted under oath that he is not qualified to offer them. (*Id.* 45:14-46:3.)

C. DR. BALES'S OPINIONS REGARDING THE TVT-O DEVICE MUST BE LIMITED IN KEY RESPECTS BY HIS DEPOSITION TESTIMONY.

Plaintiffs move that Dr. Bales testified as follows regarding the TVT-O device and that his opinions should now be limited or excluded to remain within the confines of the testimony. Specifically:

- Dr. Bales cannot offer opinions that conflict with his testimony that in his clinical practice, he is now performing more autologous sling procedures than in the past; (Ex. C, 9:4-7.)
- Dr. Bales cannot testify at trial that the efficacy of native tissue procedures, retropubic procedures, and transobturator surgeries do not have nearly the same rate of efficacy; (*id.* 12:18-19.)
- Dr. Bales cannot contradict his testimony that pain is associated with the TVT-O device which can be temporary in some patients but permanent in others; (*id.* 31:7-18; 36:2-12.)

- Dr. Bales cannot contradict his testimony that the procedure to implant the TVT-O carries a higher risk of perforating the vagina than the one to implant the TVT; (*id*. 34:8-35:2.)
- Dr. Bales testified on the record that he will not offer any opinions whether surgeons should have minimal requirements from hospital credentialing or professional societies before they are allowed to implant mesh devices and cannot do so at trial; (*id*. 41:2-7.)
- Dr. Bales offered the opinion that early versions of Ethicon's Instructions For Use ("IFU") were inadequate in certain key respects including failing to inform physicians that mesh slings could potentially need to be removed and that dyspareunia could result from vaginal mesh implants. He may not testify to the contrary at trial; and (*id*. 96:4-13; 99:5-15.)
- Dr. Bales cannot now offer testimony saying he disagrees with certain opinions proffered by Plaintiffs' expert, Dr. Jerry Blaivas, including that pain is a poorly-studied complication of mesh surgery, (*id*. 78:18-23) that chronic pain is one of the most common indications for the removal of mesh devices, (*id*. 79:9-80:10) and that even explants do not always result in pain resolution. (*Id*. 83:14-18.)

V. CONCLUSION

For reasons of the forgoing, the opinions of Dr. Bales, as set forth herein, must be excluded as they do not meet the standard governing expert opinion set forth by federal law.

Date: April 21, 2016.

By: /s/ Fidelma L. Fitzpatrick

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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